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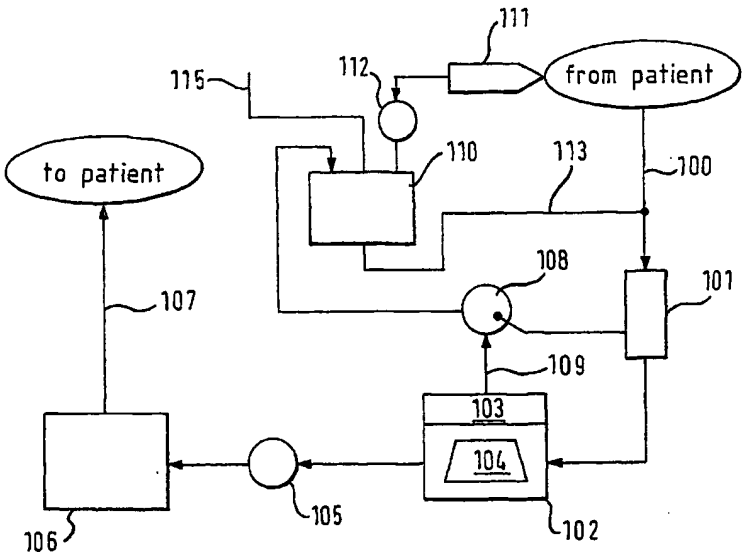
[Continued on next page]

(54) Title: AUTOMATIC AIR REMOVAL SYSTEM



(57) Abstract: According to the invention, an apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery comprises a bubble sensor 101, arranged at or connected to a venous line 100, for detecting bubbles in the venous blood received from the patient. When air bubbles are detected a second pump 109 is activated to draw air from an air chamber 103 provided in an air filter 102 connected to the venous line 100 and arranged downstream of said bubble sensor 101. A first pump 105 draws the blood from the air filter 102 and supplies the blood to an oxygenator 106 and to the patient via arterial line 107.

WO 2005/067998 A1

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

FIELD OF THE INVENTION

This invention relates to a method and an apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery, and more particularly to an automatic air removal system.

BACKGROUND OF THE INVENTION

During cardiopulmonary bypass surgery the patient's blood is pumped through an extracorporeal blood circuit conventionally comprising a venous drainage line, a venous reservoir, a blood pump, an oxygenator, and an arterial filter. Blood is drained from the patient through the venous drainage line into the venous reservoir. The blood pump draws blood from the reservoir and supplies the blood to the patient via the oxygenator and the arterial filter. The venous reservoir as well as the arterial filter removes air bubbles from the blood, which may otherwise pose a serious risk to the patient's life if returned to the patient in the arterial blood flow.

To avoid the venous reservoir an extracorporeal blood circuit may comprise, as described in US 6.524.267, an arterial filter especially adapted to comprise an air chamber, an purge port having an increased size for allowing a vacuum to actively purge air from the air chamber, a check valve being incorporated into the purge port to prevent air or blood from a cardiotomy reservoir from being drawn into the arterial filter by the negative pressure in the arterial filter, when the purging vacuum is not active, and an air sensor being connected to activate the purge vacuum when, and only when, air is present in the air chamber of the arterial filter.

Arterial filters are known in the art, for example from US 5.632.894, US 4.676.771, US 4.572.724, and US 4.411.783. However, conventional air filters cannot be used in the above

second extracorporeal blood circuit although it would be cost saving if conventional components can be used in setting up extracorporeal blood circuit.

SUMMARY OF THE INVENTION

The present invention provides a method and an apparatus for extracorporeal oxygenation of a patient's blood during, for example, cardiopulmonary bypass surgery, without the necessity to provide a venous reservoir, improved in that conventional arterial filters may be used thereby avoiding the necessity to provide adapted components.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of a first conventional apparatus for extracorporeal oxygenation of a patient's blood;
FIG. 2 is a schematic diagram of a second conventional apparatus for extracorporeal oxygenation of a patient's blood;
FIG. 3 is a schematic diagram of a third conventional apparatus for extracorporeal oxygenation of a patient's blood;
FIG. 4 is a schematic diagram of a first apparatus for extracorporeal oxygenation of a patient's blood according to the invention; and
FIG. 5 is a schematic diagram of a second apparatus for extracorporeal oxygenation of a patient's blood according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As schematically shown in FIG. 1, a conventional heart-lung equipment comprises pump means 1 for drawing the blood of a patient during cardiovascular surgery through a venous line 2 and supplying it to an oxygenator 3. The oxygenated blood is returned to the patient through an arterial line 4. Cardiotomy blood is collected by a suction device 5 and is delivered to a cardiotomy reservoir 6 by a suction pump 7 connected to the suction device 5.

In the above conventional extracorporeal blood circuit, venous blood from the venous line 2, as well as defoamed and filtered cardiotomy blood from the cardiotomy reservoir 6, is supplied to a venous reservoir 8 where air entrapped in the blood is separated by allowing the air to rise to the surface of the blood in the reservoir 8. The separated air is vented to atmosphere through an exhaust line 9.

The blood supplied by pump means 1 to the oxygenator 3 is supplied from the oxygenator 3 to an arterial filter 10 and further to the arterial line 4. The arterial filter 10 is basically a bubble trap for separating bubbles from the blood and discharging the air of the bubbles to atmosphere through an exhaust line 11.

To avoid the venous reservoir 8 in order to reduce the priming volume of the extracorporeal blood circuit, it has been proposed, as shown in FIG. 2, to provide a bubble trap filter 10 in the venous line 2 upstream of the pump means 1. The venous blood and the blood from the suction means 5 is supplied to the bubble trap filter 10. The air separated from the blood supplied to the bubble trap filter 10 is discharged to atmosphere via exhaust line 11. The blood is pumped from the bubble trap filter 10 to the oxygenator 3 and further to the patient via arterial line 4. The negative pressure generated by the pump means 1 assists to draw blood from the patient into the bubble trap filter 10.

Alternatively, as shown in FIG. 3, it has been proposed to supply the blood of the bubble trap filter 10 and of the cardiotomy reservoir 6 to pump means 1 for being pumped to the oxygenator 3 and to the patient via arterial line 4. Further, a modification of conventional bubble trap filters has been proposed to connect further pump means 12 to the bubble trap filter 10 to draw air from the bubble trap filter 10 via an adapted exhaust line 11. The same further pump means 12 are proposed to draw air also from the cardiotomy reservoir 6. To prevent air or blood from being drawn from the cardiotomy reservoir 6 into the bubble trap filter 10, a check valve 13

is provided in the modificated bubble trap filter 10 to be arranged in the exhaust line 11 upstream of the further pump means 12. Further, an air sensor 14 is provided in the modificated bubble trap filter 10 and is connected to activate said further pump means 12 when, and only when, air is present in the bubble trap filter 10.

According to the invention described herein, as shown in FIG. 4, the improved apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery comprises a venous line 100 for receiving venous blood from a patient and a bubble sensor 101 for detecting bubbles in the venous blood in the venous line 100. An air filter or bubble trap filter 102 is connected to the venous line 100 downstream of the bubble sensor 101 and comprises an air chamber 103 for receiving air and diverting means 104 for diverting the air entering the filter 102 into the air chamber 103. A first pump 105, defining a first vacuum, draws the blood through the venous line 100 from the air filter 102 and supplies the blood to oxygenator 106 and to the patient via arterial line 107.

The bubble sensor 101 is arranged to activate a second pump 108, defining a second vacuum, for drawing air from the air chamber 103 of the air filter 102 via exhaust line 109. The second pump 108 is activated for a predetermined time, for example 5 seconds, when bubbles are detected in the venous blood, i.e. when the bubble sensor 101 generates a signal indicating the presence of bubbles in the venous blood. Due to the second vacuum, air diverted into the air chamber of air filter 102 is drawn from the air chamber 103 and preferably supplied to a cardiotomy reservoir 110 receiving also the blood from a suction device 111 via suction pump 112.

The filtered and defoamed blood from the cardiotomy reservoir 110 is supplied to venous line 100 through supply line 113 due to the first vacuum defined by first pump means 105.

In the above arrangement according to the invention conventional components can be used to assemble the improved

apparatus for extracorporeal oxygenation of a patient's blood described herein. Especially, a conventional air filter or bubble trap filter can be employed together with a bubble sensor for the controlling of the activation of a pump to actively draw air from the air filter or bubble trap filter in order to automatically remove the air.

An alternative embodiment of the apparatus according to the invention is schematically show in FIG. 5 which largely corresponds to FIG. 4 so that the repeated description of corresponding aspects can be omitted by reference to the above description relating to FIG. 4. The apparatus shown in FIG. 5 further comprises a third pump 114, defining a third vacuum, arranged in the supply line 113 to actively draw blood from the cardiotomy reservoir 110 and supply the blood to venous line 100. The bubble sensor 101 is adapted to activate for a predetermined time also the third pump 114 when bubbles are detected in the venous blood, i.e. when the bubble sensor 101 generates a signal indicating the presence of bubbles in the venous blood. Due to the third vacuum, the supply of blood to the venous line 100 is assisted and not only caused by the first vacuum defined by the first pump 105.

In both embodiments of FIG. 4 and 5, a fourth vacuum is preferably applied to exhaust line 115 of the cardiotomy reservoir 110 for drawing air from the reservoir.

It is understood that the exemplary apparatus described herein and shown in FIG. 4 and 5 of the drawings represents only a presently preferred embodiment of the invention. Various modifications and additions may be made to such embodiment without departing from the spirit and scope of the invention. Other modifications and additions may be obvious to those skilled in the art and may be implemented to adapt the present invention for use in a variety of different applications.

CLAIMS

1. A method for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery, the method comprising:
   - receiving venous blood from a patient into venous line means;
   - pumping venous blood through an air filter connected to said venous line means by means of a first vacuum, generated by a first pump means, the air filter comprising an air chamber;
   - diverting air entering said air filter into said air chamber;
   - sensing bubbles in the venous blood;
   - applying a second vacuum to said air chamber, for drawing air from said air chamber, only when bubbles are sensed in the venous blood;
   - pumping blood exiting the air filter through the first pump means and through blood oxygenating means to oxygenate the blood; and
   - returning the blood oxygenated by said blood oxygenating means to an arterial system of said patient.

2. The method according to claim 1 further comprising delivering the air drawn from said air chamber to a cardiotomy reservoir.

3. The method according to claim 2 further comprising applying a third vacuum to said cardiotomy reservoir for drawing blood from said cardiotomy reservoir and for supplying the blood to the venous line means.

4. The method according to claim 2 or 3 further comprising applying a fourth vacuum to said cardiotomy reservoir for drawing air from said cardiotomy reservoir.

5. The method according to one of claims 1, 2, 3 or 4 further comprising generating the second vacuum by a second pump means and actuating the second pump means only when bubbles are

sensed in the venous blood.

6. The method according to one of claims 1, 2, 3, 4 or 5, wherein venous blood is not collected in a venous reservoir.

7. Apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery, the apparatus comprising:
   - venous line means for receiving venous blood from a patient;
   - bubble sensing means, arranged at or connected to said venous line means, for detecting bubbles in the venous blood received from said patient;
   - air filter means, connected to the venous line means and arranged downstream of said bubble sensing means, for separating air from blood, the air filter means comprising an air chamber for receiving air and means for diverting the air entering said air filter means into said air chamber;
   - blood oxygenating means for oxygenating blood after passing through the air filter means;
   - arterial line means for returning blood to the arterial system of said patient after the blood has been oxygenated by the blood oxygenating means;
   - first pump means, defining a first vacuum, for pumping blood through said venous line, said air filter means, said the blood oxygenating means and said arterial line means; and
   - second pump means, defining a second vacuum, to draw air from the air chamber of said air filter means only when bubbles are detected in the venous blood by the bubble sensing means.

8. Apparatus according to claim 7, wherein an outlet port of said second pump means is connected to a cardiotomy reservoir, said cardiotomy reservoir being connected to said venous line means upstream of said bubble sensing means.

9. Apparatus according to claim 7 or 8, wherein a third pump means is provided for defining a third vacuum which is applied to said cardiotomy reservoir for drawing blood from said cardiotomy reservoir and for supplying blood from the cardiotomy reservoir to the venous line means.

10. Apparatus according to claim 7, 8 or 9, wherein a fourth vacuum is applied to said cardiotomy reservoir for drawing air from said cardiotomy reservoir.

11. The method according to one of claims 7, 8, 9 or 10 wherein said bubble sensing means are connected to said second pump means for actuating said second pump means only when bubbles are sensed in the venous blood.

Fig. 1
prior art

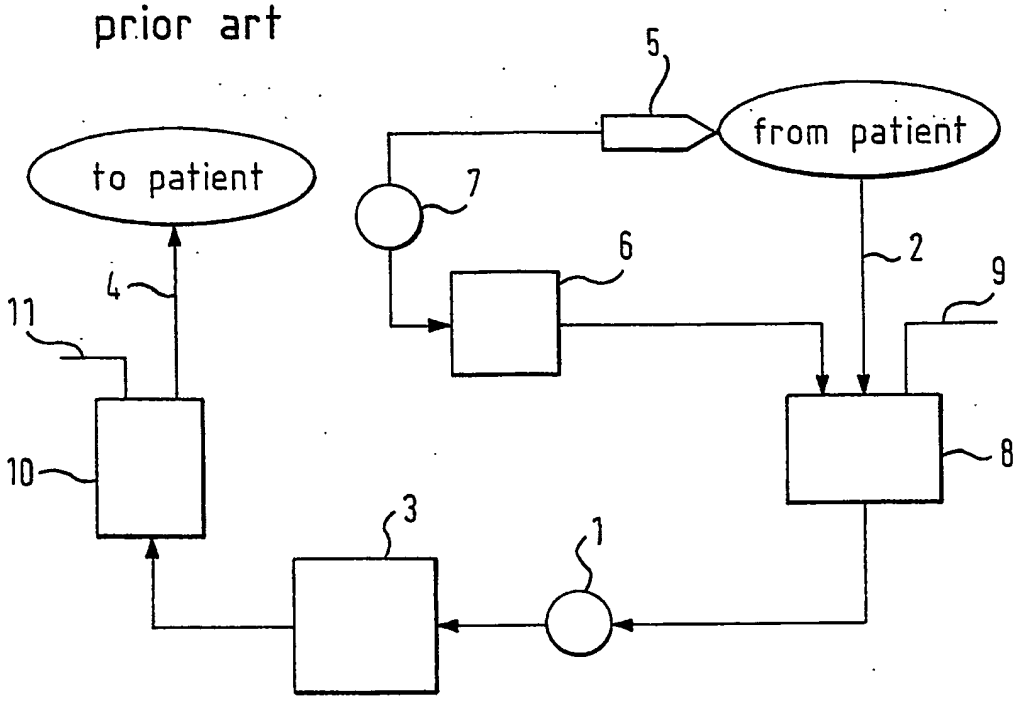


Fig. 2
prior art

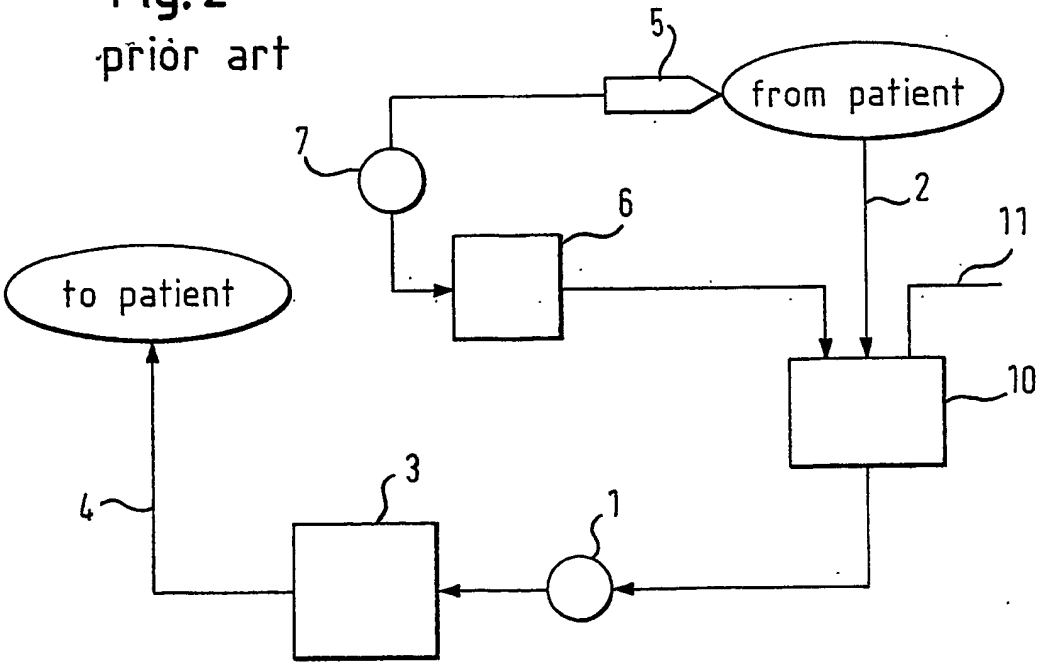


Fig. 3
prior art

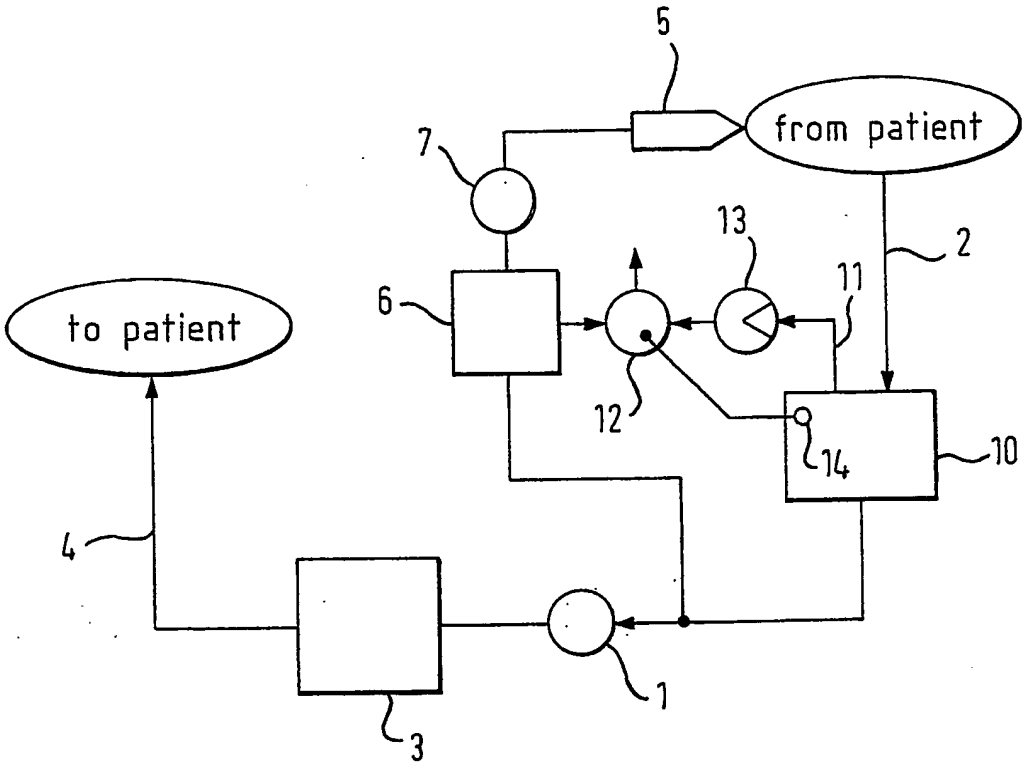


Fig. 4

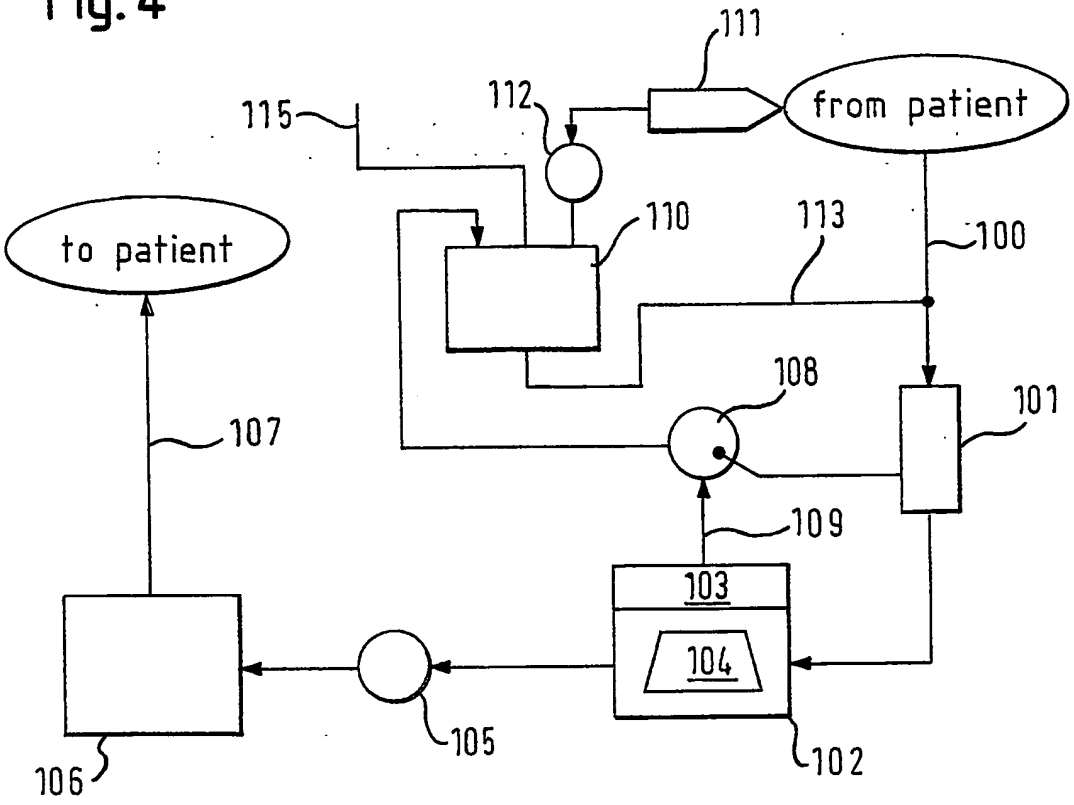

111
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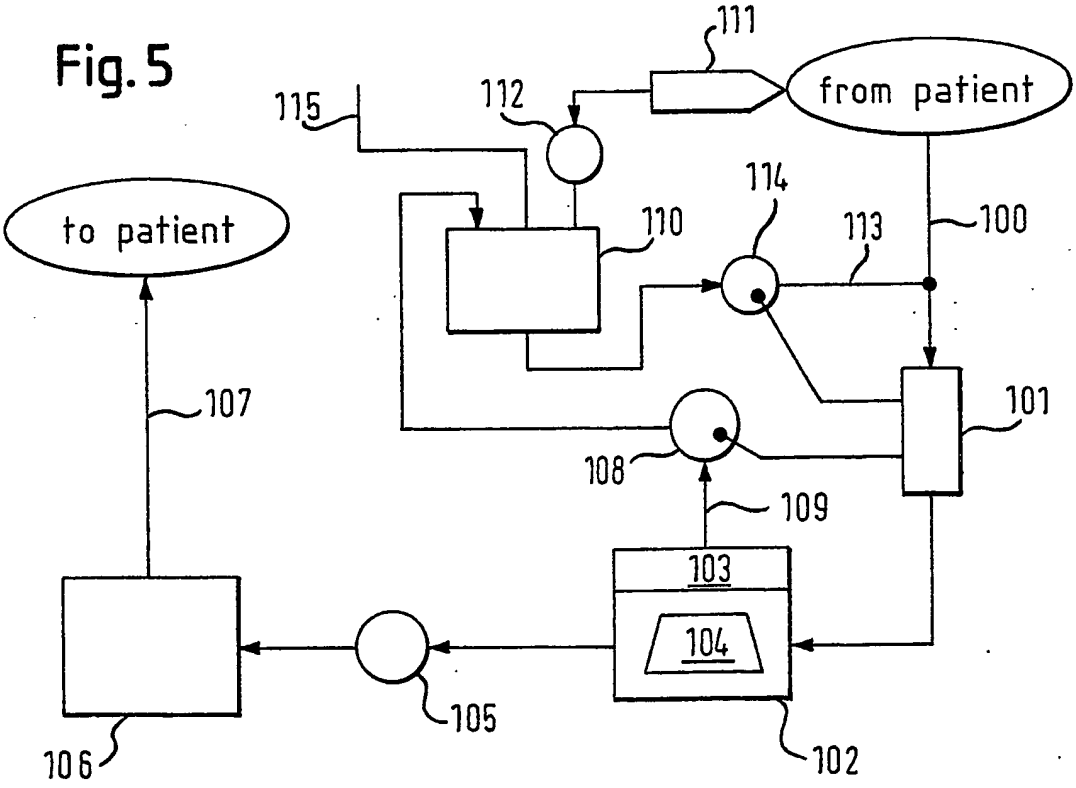
Fig. 5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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2005/000536

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 1 374 929 A (JOSTRA AG) 2 January 2004 (2004-01-02) paragraph '0015! - paragraph '0017!; figure	7,11 8-10
Y	US 6 337 049 B1 (TAMARI YEHUDA) 8 January 2002 (2002-01-08) paragraph '0062!; figure 1	8
Y A	US 6 632 189 B1 (MARTINET ALPHONSE ET AL) 14 October 2003 (2003-10-14) paragraph '0050! - paragraph '0051!; figure 6	9 10
Y	US 6 524 267 B1 (ELGAS ROGER J ET AL) 25 February 2003 (2003-02-25) cited in the application paragraph '0016!; figure 1	10
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2005	18/05/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP2005/000536

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 203 592 A (CONVERGENZA AG) 8 May 2002 (2002-05-08) paragraph '0017!	
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2005/000536

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-6
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgeryRule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP2005/000536

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